REMARKS

Claims 1 to 44 are in the case, of which claims 6-12, 14-36, 38, 40 and 42 have been withdrawn from consideration. Claims 1-5, 13, 37, 39, 41, 43 and 44 are currently before the Examiner.

Claims 1-5, 13 and 44 have been amended in view of the Office Action and to better define what the Applicants consider their invention, as fully supported by an enabling disclosure.

No new matter has been added.

Reconsideration in view of the following remarks and entry of the foregoing amendments are respectfully requested.

NEW OBJECTIONS/REJECTIONS

The Examiner has rejected claims 37, 39, 41 and 43 under 37 CFR 1.75(c).

Applicant amends the claims to place the claims in proper dependent form.

In view of the above and foregoing, it is respectfully requested that the Examiner withdraw her objections to claims 37, 39, 41 and 43 under 37 CFR 1.75(c).

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-5, 13 and 44 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The rejection was one of new matter.

Applicants respectfully traverse the rejection. However, to accelerate prosecution towards allowability, Applicant amends the claims to ensure compliance with 35 U.S.C. § 112, first paragraph. More specifically, the claims now recite that a unimodal peak location corresponding to a target pore diameter. The numerical values are phraseology of the claim limitations are fully supported by paragraphs [91] to [98] and Figures 13 to 16.

The fact that a majority of pores of an article according to the present invention has a diameter within ±50% of the chosen pore diameter graphically appears on distribution curves as shown on Figures 13 to 16. Indeed, drawing two vertical lines at values of diameters d corresponding to:

$d = d_v$ (chosen pore diameter) + d_v*50% and

$d = d_v - d_v$*50%,

allows verifying that the so defined area under the curve of incremental volume represents more than 50% of the total void volume.

An example would be as follows: in Figure 15 if the peak height is taken as 14 microns then the plus or minus 50% values become 21 and 7 microns respectively. If those interval values are then marked off on Figure 15 (please see attachment) it can be readily seen that the area under the curve of incremental volume represents more than 50% of the total void volume. Note that the total void volume can be represented by the total area under the curve. The shaded area represents the part of the curve within the plus or minus 50% limit. In the case of Figure 15 clearly almost all of the curve, clearly more than the majority, is within the plus or minus 50% limits thus satisfying claim 1.

Similarly, as shown in the attached mark-up of Figure 15, support is found for the majority being within the plus or minus 40% and 25%.

In view of the above and foregoing, it is respectfully requested that the Examiner withdraw her rejection of claims 1-5, 13 and 44 under 35 U.S.C. § 112, first paragraph.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-5, 13 and 44 have been rejected as being indefinite under 35 U.S.C. §

112, second paragraph.

Applicants respectfully traverse the rejection as follows.

Applicants amend the claims to recite features commensurate with the application as filed as requested by the Examiner .

In view of the above and foregoing, it is respectfully requested that the Examiner withdraw her rejection of claims 1-5, 13 and 44 under 35 U.S.C. § 112, second paragraph.

DOUBLE PATENTING

Claims 1 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 19, 26, 28, 30 of co-pending Application No. 12/093712.

This rejection is provisional since the conflicting claims have not in fact been patented.

Applicants duly noted this provisional rejection but does not wish to address it at this time. Applicants recognize that this objection may continue to be made by the Examiner in this application, as long as she is of the opinion that there are conflicting claims in the two applications that are the subject of this rejection, subject to the following: "If this "provisional" non statutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the latter is rejectable on other grounds, the Examiner should withdraw that rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer" (MPEP 804 I.B.1).

As indicated previously, the present application is the earlier filed of the two applications that are the subject of the present rejection. Applicants therefore do not wish to address this issue in the present response since the provisional rejection may be withdrawn.

REJECTION UNDER 35 U.S.C. § 102

Claims 1-4, 13 and 44 have been rejected as being anticipated by **Washburn *et al.***

Applicants respectfully traverse the rejection as follows.

Applicants amend the claims to more precisely recite the invention, as supported by the application as filed.

Washburn *et al*. teach porous materials with "characteristic pore size that may be increased to larger than 100 micrometers", that have " continuous void space and controlled characteristic length scales" (see abstract). In relation to Figure 4, porous materials with 70 % porosity and a characteristic void space length scale close to 100 micrometers, and pore diameters ranging from 20 to 150 micrometers are described (page 25 left column). In relation to Figure 5 pointed out by the Examiner, porous materials with 50 % porosity and a characteristic void space length scale of 20 micrometers, and pore diameters ranging from 10 to 100 micrometers are described (page 26 left column). Thus **Washburn *et al***. describe porous materials which characteristic length scale of the void space can be continuously varied up to 100 micrometers (see page 28 right column).

Meanwhile, the present invention teaches microporous polymeric article having a target pore diameter d_v, i.e. a unimodal pore diameter distribution, defined at paragraph [0065] as being a distribution having a single local peak, set a predefined unimodal peak location d_v (see abstract, paragraphs [0051], [0071], [0091]-[0096]. Figures 13 to 16 show examples of such materials:

- Figure 13a shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_v= 1.0 micrometer.
- Figure 13b shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_v= 1.3 micrometers.
- Figure 14a shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_v= 2.3 micrometers.

- Figure 14b shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_V= 3.3 micrometers.
- Figure 15a shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_V= 1.5 micrometers.
- Figure 15b shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_V= 14 micrometers.
- Figure 16a shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_V= 64 micrometers.
- Figure 16b shows the unimodal pore diameter distribution of a microporous polymeric article having a predefined unimodal peak location d_V= 72 micrometers.

Narrow, unimodal pore size distributions are fundamental to a number of applications. It is not sufficient to have simply any distribution of pore sizes. For example in tissue engineering, pore sizes of 100 microns could be required to grow cells which are of 50 micron diameter. In that case, too many pores below 50 microns will not contribute to the usefulness of the device since the cells would not even be able to enter those pores. In that case the cells grow and then cell growth is “stopped” by a too small pore size. Narrow pore size distributions are also important, for example, in drug delivery applications where a controlled time release is required. If a particular uniform time interval of release is required then the pore size distribution becomes a controlling factor. Hence porous materials containing pores with narrow, unimodal size distributions are critical to a number of applications. Obtaining narrow pore size distributions requires significant control over the structure of constituent materials and is a non-trivial objective.

It is noted that in the Washburn paper pore size distributions are not reported. Also, the samples in the Washburn paper typically have one structure at the surface of the sample and another in the interior. For example the text describing Figure 5a) (page 25) indicates that 20 micron pores are observed at the surface while larger 100 micron pores are observed in the interior. This indicates that this sample will have a bimodal distribution as opposed to unimodal distribution. By definition, one distribution for pores at the surface and

another for pores in the interior cannot possibly yield a unimodal distribution for the device as a whole. The pore size distribution of the device in Washburn cannot possibly be unimodal since typically two morphologies are observed.

The present application reports unique structures with a high degree of control over: 1) the level of continuity of the porosity; 2) the void volume of the porous part; and 3) with significant control over the modality and width of the pore size distribution. The claimed features were heretofore unknown.

The standard for anticipation is one of fairly strict identity: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), and "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applying this standard, it is clear that the claimed features are not provided in the cited references. Despite overlapping pore size intervals, it is clear that the cited references do not provide the unimodal and narrow pore size distributions as claimed herein. Such difference shows that the claimed unimodal and narrow pore size distributions are not found either expressly or inherently in a prior art reference.

Washburn *et al*. mention a maximum pore size ("above 100 microns" -see Abstract), and pore size ranges from 20 to 150 microns (page 25, column 1) and from 10 to 100 microns (page 26, column 1). **Washburn *et al***. do teach porous materials having a range of pore sizes. However, **Washburn *et al***. fail to teach porous materials with pore diameters showing a unimodal distribution set to a predefined unimodal peak location corresponding to a chosen pore diameter and a majority of pores having a diameter within at most ± 50% of the chosen pore diameter as described and recited in the present application.

From the foregoing, as **Washburn *et al***. fail to describe, either expressly or inherently, each and every element recited in independent claims 1 and 13, it is respectfully submitted that the Examiner withdraw her rejection of independent claims 1 and 13 and claims dependent thereon.

Claims 1-5, 13 and 44 have been rejected as being anticipated by **5,856,367 ('367)**.

Applicants respectfully traverse the rejection as follows.

'367 describes porous articles with pores having an average size between 0.5 and 50 microns and between 300 and 500 microns (see column 8 lines 34-48), or pores greater than about 200 microns (see column 8 line 44), or pores greater than about 300 microns (see column 8 line 48), or pores ranging from 5 to 30 microns (see example 1 column 9 line 39), pores of 5 to 50 microns (example 2 column 10 line 35), or with larger pores from 300 to 500 microns (column 10 line 47), or pores of greater than 300 microns combined with pores in the range of 5 to 20 microns (See column 3 lines 32-35); pores from 5 to 50 microns (See example 6 pointed out by the Examiner column 14 line 1). **'367** does not teach porous articles having a target pore diameter d_v and a unimodal distribution set to a predefined unimodal peak location corresponding to this target pore diameter d_v as defined and claimed in the application.

As **'367** fails to describe, either expressly or inherently, each and every element as set forth in independent claims 1 and 13, it is respectfully submitted that the Examiner withdraw her rejection of independent claims 1 and 13 and claims dependent thereon.

Claims 1-5, 13 and 44 have been rejected as being anticipated by **6,281,257 ('257).**

Applicants respectfully traverse the rejection as follows.

'257 teaches porous materials with a desired porosity (see definition column 3 lines 49-54), in terms of void volume: the void volume is of at least 80% (see column 2, lines

21-32 and examples in section 4 starting in column 13). The pore sizes obtained are of several microns up to about 300 microns (see column 7, lines 54-55), 50-200 microns (column 8, lines 19-20), up to 600 microns (see column 10, line 14). '**257** fails to teach porous articles having a having a target pore diameter d_v and a unimodal distribution set to a predefined unimodal peak location corresponding to this target pore diameter d_v as defined and claimed in the application.

As '**257** fails to describe, either expressly or inherently, each and every feature as recited in independent claims 1 and 13, it is respectfully submitted that the Examiner withdraw her rejection of independent claims 1 and 13 and claims dependent thereon.

Claims 1-4, 13 and 41 have been rejected as being anticipated by **2002/0005600 ('600)**.

Applicants respectfully traverse the rejection as follows.

The Examiner points out that '600 teaches porous articles with void volumes of at least 80%, and a pore size controlled in the range of 100-500 micrometers with a maximum yield at around 300 micrometers (page 7 paragraph [0091]). However, it is important to note that paragraph [091] demonstrates the size of parafin spheres that are eventually heat bonded together to form a porous material. The sizes reported in paragraph [091] are for those paraffin spheres - at that point no porous material has even been formed. In paragraph [092] a heat treatment is imposed to bond the spheres, but no measurement of the actual porous structure is examined. Only a rather poor photo of that structure is shown in Figure 2.

In paragraph [096] Figures 4a,b are described. It is noted that the polymer skeleton in those figures demonstrate very small micropores in addition to the large pores. These very small micropores in the polymer skeleton in addition to the large macropores are referred to in the last 7 lines of paragraph [096]. This is a bimodal distribution as opposed to the unimodal distribution of the present claims. This is a very different structure from the controlled unimodal distribution claimed in the present application.

Thus, **'600** fails to teach such a unimodal peak location corresponding to a chosen pore diameter.

As **'600** fails to describe, either expressly or inherently, each feature as recited in independent claims 1 and 13, it is respectfully submitted that the Examiner withdraw her rejection of independent claims 1 and 13 and claims dependent thereon.

The rejections of the claims are believed to have been overcome by the present remarks and amendments. From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such an action is earnestly solicited.